COOPERATIVE BIOLOGICAL ENGAGEMENT PROGRAM (CBEP) PROTOCOL RISK ASSESSMENT TOOL

NOTE: Microsoft Excel 2007 or later is recommended. Using this tool with earlier versions of Excel may cause limited functionality.

General Information:

The CBEP Protocol Risk Assessment Tool (PRAT) is to be completed when submitting laboratory protocols and research proposals involving infectious or potentially infectious materials. The purpose of this form is to ensure research funded by CBEP (or other CBEP-sponsored laboratory activity) is conducted safely, securely and responsibly. For protocols that involve potentially high-risk activities (i.e., work performed at BSL3 or 4), CBEP may request supplemental information for a secondary review such as facility-specific site assessments and design specifications, and project-specific SOPs.

It is the responsibility of the Principal Investigator (PI) or other appropriate laboratory manager or supervisor to complete this form, in close collaboration with biorisk management advisors (i.e., biosafety officer, security officer, safety manager), after conducting a comprehensive risk assessment. A number of factors must be carefully considered in order to adequately assess risk including the characteristics of the agents/samples, the equipment that will be used, the procedures to be performed, the involvement of animals, the containment and security of available facilities, and the capabilities of the laboratory staff. Information in the following publications should be used as references to develop the risk assessment:

- *WHO Laboratory Biosafety Manual, 3rd Edition*
- *WHO Biorisk Management: Laboratory Biosecurity Guidance, September 2006*
- *World Organization for Animal Health (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 7th Ed. 2012*
- *Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition*
- *Public Health Agency of Canada's Pathogen Safety Data Sheets*
- *NIH Guidelines for Research Involving Recombinant DNA Molecules*
- *Occupational Health and Safety in the Care and Use of Research Animals*
- *DOD Instruction 3216.1 Use of Laboratory Animals in DOD Programs*

Click here to Acknowledge these instructions and Continue

FOR CBEP BIOSAFETY AND BIOSECURITY (BS&S) USE ONLY

Display BS&S Assessment Summary and Recommendations

COOPERATIVE BIOLOGICAL ENGAGEMENT PROGRAM (CBEP) PROTOCOL RISK ASSESSMENT TOOL

NOTE: Microsoft Excel 2007 or later is recommended. Using this tool with earlier versions of Excel may cause limited functionality.

Specific Instructions:

- *Please respond to all questions/statements.*
- *If prompted (or in the Excel Options), ensure macros are Enabled when opening this form.*
- *You may Save and Close the file at any time, and resume at a later time.*
- *The PRAT is made up of the Main Form and several attachments. The attachments (sub-forms) will be accessed and visible when necessary.*
- *Responses to the information requests on this form will be entered by either typing information into a response box (cell) or by using a drop-down arrow to select the appropriate response from a list of options. Simply click on a response box (cell) with your mouse and enter the appropriate response. You may also use the <TAB>, <ENTER>, and arrow keys to navigate through the response boxes.*
- *All primary response boxes (cells) are highlighted in yellow.*
- *Some responses cause additionally-required responses or information; these data boxes (cells) will automatically highlight in yellow as needed.*
- *Macro "buttons" are used throughout the PRAT to help the user navigate between the main form and the various attachments when additional information is required. Simply click on the buttons when necessary and/or directed to do so.*
- *Depending on your version of Excel, you can enlarge your viewing window by hiding the Menu Ribbon. Hold down the <CTRL> key and press the <F1> key. Repeat to unhide the ribbon.*
- *At any time, the user may Preview and/or Print the PRAT, entirely or separately by Main Form and attachments, by following the Printing Instructions below.*
- *For technical and other questions concerning this Protocol Risk Assessment Tool, contact:*

  James "JD" Dornak - E-mail: james.dornak_contractor@dtra.mil

- *Click on the button below to access the Main Form and begin the PRAT. The General and Specific Instructions will remain visible throughout the assessment process. Click on the tabs at the bottom of the Excel window to view these instructions as needed.*

Click here to access the Biorisk Assessment (Main) Form

Printing Instructions (Microsoft Excel Version)

- *To Preview and/or Print parts or all of this Protocol Risk Assessment Package, follow the below instructions:*

  1) Save this file using the "Save" or "Save as…" menu option.

  2) Click on the desired button below and follow your computer's Preview/Printing directions.

General and Specific Instructions

Protocol Risk Assessment Package w/ Cover Sheet

Biorisk Assessment (Main Form)

Attch 1 - Project Facilities Information

Attch 2 - Key Personnel Infomation

Attch 3 - Samples and Agents Infomation

Attch 4 - Select Agents Exclusion List

Attch 5 - rDNA Infomation

Attch 6 - OTCC Infomation

Attch 7 - Chemicals Infomation

Attch 8 - Biosafety Cabinet Infomation

Attch 9 - IACUC Infomation

Attch 10 - IRB Infomation

Appendix 1 - Select Agents List

COOPERATIVE BIOLOGICAL ENGAGEMENT PROGRAM (CBEP)
PROTOCOL RISK ASSESSMENT TOOL

Project Number:

Not Provided

Project Title:

Not Provided

Projected Start Date:

Not Provided

Principal Investigator Attestation signed by:

Not Provided
(signed on)

This Protocol Risk Assessment Package printed on:

May 9, 2013

CBEP PROTOCOL RISK ASSESSMENT TOOL

It is the responsibility of the Principal Investigator (PI) or other appropriate laboratory manager/supervisor to complete this form, in close collaboration with biorisk management advisors (i.e., biosafety officer, security officer, safety manager), after conducting a comprehensive risk assessment.

Please respond to all questions/statements

For protocols that involve potentially high-risk activities (i.e., work performed at BSL3 or 4), CBEP may request supplemental information for a secondary review such as facility-specific site assessments and design specifications, and project-specific SOPs.

1. GENERAL INFORMATION:

a) Project Number (from Form A):	
b) Project Title (from Form A):	
c) Projected Start Date:	

d) Project/Protocol Summary: (briefly summarize the proposed project/protocol and its goals)

e) Project Facility Information:

Click here to add/edit Project Facility Information

Project Facility #1	
Facility Name (Location):	***Not Provided***
Principal Investigator (Contact Information):	***Not Provided***
Project Facility #2	
Facility Name (Location):	***N/A***
Principal Investigator (Contact Information):	***N/A***
Project Facility #3	
Facility Name (Location):	***N/A***
Principal Investigator (Contact Information):	***N/A***

f) Laboratory Information: (list individual laboratory areas, their BSL, use, and containment equipment)				
Building/Room Number(s)	**Biosafety Level**	***Use of Room***	***Equipment***	
				Biosafety Cabinet
				Fume Hood
				Autoclave
				Biosafety Cabinet
				Fume Hood
				Autoclave
				Biosafety Cabinet
				Fume Hood
				Autoclave
				Biosafety Cabinet
				Fume Hood
				Autoclave
				Biosafety Cabinet
				Fume Hood
				Autoclave
				Biosafety Cabinet
				Fume Hood
				Autoclave

g) Research Protocol Workflow Summary: (briefly describe the project's workflow)
This summary should detail the major steps in the research protocols to include work flow sequencing of project-specific SOPs and description of primary tasks.

h) Key Personnel Information: (i.e.. Laboratory Manager, Laboratory Technicians, etc.)	
Click here to add/edit Key Personnel Information	
Key Person #1	
Key Person's Name (Contact Information):	***Not Provided***
Job Title, Institute:	***Not Provided***
Position/Role in this project:	***Not Provided***
Key Person #2	
Key Person's Name (Contact Information):	***N/A***
Job Title, Institute:	***N/A***
Position/Role in this project:	***N/A***
Key Person #3	
Key Person's Name (Contact Information):	***N/A***
Job Title, Institute:	***N/A***
Position/Role in this project:	***N/A***
Key Person #4	
Key Person's Name (Contact Information):	***N/A***
Job Title, Institute:	***N/A***
Position/Role in this project:	***N/A***
Key Person #5	
Key Person's Name (Contact Information):	***N/A***
Job Title, Institute:	***N/A***
Position/Role in this project:	***N/A***

2. PROTOCOL RISK ASSESSMENT:

a) Does this project involve Biological Materials of any type? (Human, Animal, Plant, Environmental, or Isolated Cultures): [ ]

If "Yes", complete the information tables below

Sample / Agent Involved in Project	Select Agent	Material / Sample	Material Status	To Be Cultured	Infected Host/Model

If necessary, click here to view the Select Agents and Toxins List

BELOW: List other Samples/Agents not found on the above Sample/Agent Drop-Down List
(Do NOT list Excluded or Exempt Select Agents/Toxins, rDNA, OTCC,
or Chemicals Administered to OTCC - they are addressed in next sextion)

If there are any Biological Materials listed above,
Click here to complete the Samples/Agents Information Tables

Other Research Materials	
Excluded or Exempt Select Agents and Toxins? (see below):	
Click here to go to the Excluded Select Agents List, to identify any such agents used in this	
Recombinant DNA (rDNA)? (see below):	
If above statement is "Yes", click here to complete the rDNA information table	
Organism, Tissue, or Cell Cultures (OTCC)? (see below):	
If above statement is "Yes", click here to complete the OTCC information table	
Chemicals Administered to OTCC? (see below):	
If above statement is "Yes", click here to complete the Chemicals information table	

b) Activities to be conducted during this project: (enter "X" next to all that apply)	
Animal Subject Research:	
Arthropod Research:	
Human Subject Research:	
In vivo Research:	
Autopsy/Necropsy:	
Bacteriology:	
Microbiology:	
Molecular Biology:	
Parasitology:	
Sample Processing:	
Sample Transport/Shipping:	
Serology:	
Toxicology:	
Virology:	
Other activities not listed above:	

If "Other activities" above is "Yes", list/explain below:

c) Lab Equipment to be used: (enter "X" next to all that apply)		
Centrifuge:		
Sonicator:		
Aerosol Chamber:		
Homogenizer:		
Shaker:		
Vacuum/Aspirating Equipment:		
Cell Sorters:		
Pipettors:		
French Press:		
Needles (Syringes):		
Other Lab Equipment not listed above:		
If "Other Lab Equipment" above is "X", list/explain below:		

d) Do you plan to use biosafety cabinets (BSCs)?		**If BSC is "Yes", click here**

e) Additional Barrier Equipment to be used: (enter "X" next to all that apply)		
Safety Centrifuge Cups:		
Sealed Centrifuge Rotors:		
Ventilated Animal Cage Rack System:		
Filter Top Animal Cage:		
Chemical Fume Hood:		
Other barrier equipment not listed above:		
If "Other Barrier Equipment" above is "X", list/explain below:		

f) Does this project involve Animals?		**If Animals is "Yes", click here**	
g) Does this project involve Human Subjects?		**If Human Subjects is "Yes", click here**	
h) Has this project been reviewed by an Institutional Committee (i.e. IBC)?			
If an Institutional Committee Review has occurred (above answer is "Yes"), please provide the below information and include (required) the Review Committee's approved Charter and Membership List when submitting this form.			
What is the status of the Committee Review?:		Approval date:	

3. BIORISK MANAGEMENT PROGRAM:

This information refers to the facility where the protocol will be conducted and the personnel that will be directly involved in the protocol. If more than one facility will be participating in the protocol, please use this section to provide information on the primary institute and attach additional information to the form as necessary.

a) Is a biorisk management advisor (i.e., biosafety officer) being consulted for this project?		**(If "Yes", enter Name and Affiliation below)**
Name:		
Affiliation:		

b) BS&S Training completed or planned for this protocol: (enter "X" next to all that apply)	
Bioethics:	
Biorisk Assessment (Biosafety and Biosecurity):	
Biological Safety Cabinets Operation & Maintenance:	
Laboratory Spill Response:	
Personal Protective Equipment (PPE):	
Sample Collection:	
Sample Transportation and Shipping:	
Waste Handling and Disposal:	
BSL-2 Work Practices:	
BSL-2 Equipment:	
BSL-2 Facilities:	
BSL-3 Work Practices:	
BSL-3 Equipment:	
BSL-3 Facilities:	
Other BS&S Training not listed above:	

If "Other BS&S Training" above is "Yes", list/explain below:

c) Documents that are in place for this project: (enter "X" next to all that apply):		
Training Records:		
Facility Records (Validation, Certification, Commissioning):		
Equipment Records (Validation, Certification, Calibration):		
Laboratory Inspection Records:		
Material Safety Data Sheets (Chemical Safety Information):		
Facility Biorisk Assessment:		
Biorisk Management Manual:		
SOP - Personal Protective Equipment (PPE):		
SOP - Sample Collection:		
SOP - Transportation and Shipping:		
SOP - Biological Safety Cabinet Operation & Maintenance:		
SOP - Waste Handling and Disposal:		
SOP - Surface and Equipment Decontamination:		
SOP - Laboratory Spill Response:		
Project-specific SOPs (explain below):		
Other Documents not listed above:		
If "Project-specific SOPs" or "Other Documents" above is "X", list/explain below:		

4. PRACTICES, EQUIPMENT, and FACILITIES:	
a) Medical Surveillance/Occupational Health (MS/OH):	
Is there a Medical Surveillance/Occupational Health (MS/OH) Program in place for this project/protocol?:	
If "Yes" above, identify applicable MS/OH elements below. (enter "X" next to all that apply)	
Serological Testing:	
Immunizations:	
PPD Skin Test or other TB Screen:	
Medical Clearance:	
Post-Exposure Evaluation/Treatment:	
Screening/Monitoring:	
Other MS/OH Elements not listed above:	
If "Other MS/OH Elements" above is "X", list/explain below:	

b) Laboratory Equipment/Practices: (enter "X" next to all that apply)		
Laboratory seams, floors, walls, ceiling surfaces are sealed:		
Limited Access where applicable:		
Controlled Access where applicable:		
Physical separation from access corridors:		
Self-closing, double-door access:		
Entry through airlock or anteroom:		
Clothing change before entering laboratory:		
Biohazard Warning signs and labels:		
"Sharps" precautions:		
Hand washing sink near laboratory exit:		
Eyewash station available:		
Shower on exit:		
Autoclave available:		
Dunk tanks:		
Decontamination of all waste:		
Decontamination of laboratory clothing before laundering:		
All material decontaminated on exit from facility:		
Effluent decontamination:		
Exhaust air not recirculated:		
HEPA-filtered exhaust:		
Negative airflow into laboratory:		
Verification of directional airflow:		
Dedicated supply, exhaust, and vacuum systems:		
Other Equipment/Practices not listed above:		
If "Other Equipment/Practices" above is "X", list/explain below:		

5. BIOSAFETY:

a) Personal Protection Equipment (PPE) that will be used: (enter "X" next to all that apply)

Laboratory Coat:	
Solid-Front Laboratory Coat:	
Coverall or Disposable Tyvek Suit:	
Scrub Suit:	
Gloves:	
Double Gloves:	
Tyvek Sleeves:	
Safety Glasses/Goggles:	
Face Shield:	
N-95 Respirator:	
Powered Air Purifying Respirator (PAPR):	
Shoe Covers:	
Boots:	
Hair Bonnets:	
Other PPE not listed above:	

If "Other PPE" above is "X", list/explain below:

b) Methods used for Laboratory Waste Decontamination and Disposal: (enter "X" next to all that apply)

Chemical Disinfection:	
Sharps Containers:	
On-Site Autoclave:	
On-Site Incinerator:	
Packaged for Off-Site Treatment:	
Packaged for Off-Site Disposal:	
Other Methods not listed above:	

If "Other Methods" above is "X", list/explain below:

6. BIOSECURITY:

a) Are there any social, environmental, or geographical factors and/or concerns that may affect the project's/facilities' security posture?:

	If "Yes", briefly describe below:

Describe external factors or occurrences/influences which could affect facility operations (i.e., natural disasters, local crime, proximity of facility to high pedestrian/vehicle traffic areas, etc.)

b) Physical Security measures in place at the project facilities: (enter "X" next to all that apply)

Lockable Exterior (Building) Doors:	
Lockable Exterior Windows:	
Metal Grating on Ground-Accessible Exterior Windows:	
Lockable Interior (Laboratory) Doors:	
Walls/Doors/Windows have Sufficient Strength/Integrity:	
Perimeter Fencing:	
Manned Entry Control (Receptionist, Guard Station):	
Facility Access Logs:	
Visitor Sign-In Logs:	
Key and Code Control Program:	
Electronic Access Control Badge System:	
Intrusion Detection (motion detection, glass break sensors):	
Interior Monitoring/Surveillance:	
Exterior Monitoring/Surveillance:	
On-Site Security Force:	
Other Physical Security Measures not listed above:	

If "Other Physical Security Measures" above is "X", list/explain below:

c) Information Security measures in place at the project facilities: (enter "X" next to all that apply)		
Secure hard-copy data storage:		
Password protection/encryption of electronic files/computers:		
Updated anti-virus/anti-malware software on all computers:		
Network security measures in place (internal/external):		
Computers properly secured (desktops and laptops):		
Other Information Security Measures not listed above:		
If "Other Information Security Measures" above is "X", list/explain below:		

d) Material Control & Accountability (MC&A) measures in place: (enter "X" next to all that apply)		
Lockable pathogen storage containers:		
Receipt, transfer, and/or disposal of all biological material is logged and tracked:		
Pathogen Asset Control System (PACS) or equivalent laboratory inventory management system is installed, operated, and maintained:		
Periodic pathogen inventory audits:		
Other MC&A Measures not listed above:		
If "Other MC&A Measures" above is "X", list/explain below:		

e) Transport Security measures in place for this project/protocol: (enter "X" next to all that apply)		
Only authorized carriers are used for shipping/transportation:		
All shipping/transportation of biological materials is tracked:		
Biological materials are properly packaged prior to shipment:		
Chain of Custody is maintained for all Select Agents/Toxins:		
Other Transport Security Measures not listed above:		
If "Other Transport Security Measures" above is "X", list/explain below:		

f) Personnel Management measures in place for this project/protocol: (enter "X" next to all that apply)		
Personnel Suitability screening is performed:		
Biosecurity training is provided to all laboratory personnel:		
Personnel are given access to only those areas needed:		
Uncleared personnel are always escorted in restricted areas:		
Access rosters/systems are actively maintained:		
Other Personnel Management Measures not listed above:		
If "Other Personnel Management Measures" above is "X", list/explain below:		

PRINCIPAL INVESTIGATOR ATTESTATION

As the Principal Investigator (PI) of the above-titled project, and with my signature below, I attest and affirm that the below statements are true:

1. The information and responses given herein are complete, true, and accurate to the best of my knowledge.

2. All necessary and appropriate biorisk management policies, practices, procedures, training, equipment, and facilities have been put in place to ensure this project can be executed safely and securely.

3. I acknowledge and understand that appropriate notifications must be made, in writing, if there are any changes to the above information, to guarantee the continued safety and security of this project.

4. I certify that all participants working with biological materials as part of this project have received the necessary protocol-specific and annual refresher training in biosafety and biosecurity.

5. I acknowledge and understand that the Cooperative Biological Engagement Program (CBEP) may request additional information and/or documents before granting full approval of this project.

Principal Investigator	Date

Principal Investigator's Signature	

PROJECT FACILITY INFORMATION

Enter the requested information for each supporting Research Facility

When complete, click here to return to Main Page

Project Facility #1					
Facility Name:					
Street Address:				**City:**	
State/Region:		**Country:**		**Zip Code:**	
Signature Authority Name/Title:					
Telephone Number:		**Fax Number:**		**Email Address:**	
Name of Principal Investigator:					
Telephone Number:		**Fax Number:**		**Email Address:**	
Governmental Agency:					

Project Facility #2					
Facility Name:					
Street Address:				**City:**	
State/Region:		**Country:**		**Zip Code:**	
Signature Authority Name/Title:					
Telephone Number:		**Fax Number:**		**Email Address:**	
Name of Principal Investigator:					
Telephone Number:		**Fax Number:**		**Email Address:**	
Governmental Agency:					

Project Facility #3					
Facility Name:					
Street Address:				**City:**	
State/Region:		**Country:**		**Zip Code:**	
Signature Authority Name/Title:					
Telephone Number:		**Fax Number:**		**Email Address:**	
Name of Principal Investigator:					
Telephone Number:		**Fax Number:**		**Email Address:**	
Governmental Agency:					

If more space is needed, attach additional sheets

When complete, click here to return to Main Page

KEY PERSONNEL INFORMATION

Enter the requested information for all Key Personnel

When complete, click here to return to Main Page

Key Person #1					
Name:		**Job Title:**			
Institute:					
Street Address:				**City:**	
State/Region:		**Country:**		**Zip Code:**	
Telephone Number:		**Fax Number:**		**Email Address:**	
Role in this Project:					

Work Experience Relative to this Project/Role:	Start/End Dates:

Completed Training Relative to this Project/Role:	Completion Date:

Key Person #2					
Name:		**Job Title:**			
Institute:					
Street Address:				**City:**	
State/Region:		**Country:**		**Zip Code:**	
Telephone Number:		**Fax Number:**		**Email Address:**	
Role in this Project:					

Work Experience Relative to this Project/Role:	Start/End Dates:

Completed Training Relative to this Project/Role:	Completion Date:

Key Person #3					
Name:		**Job Title:**			
Institute:					
Street Address:				**City:**	
State/Region:		**Country:**		**Zip Code:**	
Telephone Number:		**Fax Number:**		**Email Address:**	
Role in this Project:					

Work Experience Relative to this Project/Role:	Start/End Dates:

Completed Training Relative to this Project/Role:	Completion Date:

Key Person #4					
Name:		**Job Title:**			
Institute:					
Street Address:				**City:**	
State/Region:		**Country:**		**Zip Code:**	
Telephone Number:		**Fax Number:**		**Email Address:**	
Role in this Project:					

Work Experience Relative to this Project/Role:	Start/End Dates:

Completed Training Relative to this Project/Role:	Completion Date:

Key Person #5					
Name:		**Job Title:**			
Institute:					
Street Address:				**City:**	
State/Region:		**Country:**		**Zip Code:**	
Telephone Number:		**Fax Number:**		**Email Address:**	
Role in this Project:					

Work Experience Relative to this Project/Role:	Start/End Dates:

Completed Training Relative to this Project/Role:	Completion Date:

If more space is needed, attach additional sheets

When complete, click here to return to Main Page

DIAGNOSTIC SAMPLES AND MICROBIOLOGICAL AGENTS

Complete BOTH tables below for each Sample/Agent listed

If more space is needed, attach additional sheets

Sample/Agent *(genus, species, strain)*	**Select Agent**	**To Be Cultured**	**Material / Sample**	**Material Status**	**Infected Host/Model**	**Toxin Production?**	**>10 Liters?**	**Recipient of rDNA Construct?**

Sample/Agent *(genus, species, strain)*	**Select Agent**	**Activities to be conducted with each listed Sample/Agent: (enter "X" next to all that apply)**			
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	
		Sample Collection	Sharps Use	Culture in Liquid Media	Other (list below)
		Cryopreservation	Injection/Inoculation	Culture on Solid Media	

When complete, click here to return to Main Page

SELECT AGENTS AND TOXINS EXCLUSION LIST

Per U.S. Dept of Health and Human Services (HHS) and U.S. Dept of Agriculture (USDA)

Use drop-down arrows to place an "X" next to all agents/toxins involved in the proposed research

	EXCLUDED HHS AGENTS & TOXINS
	Coccidioides posadasii Δchs5 strain (effective 10-14-2003)
	Coccidioides posadasii Δcts2/Δard1/Δcts3 strain (effective 03-03-2006)
	Excluded Conotoxins (effective 4-29-2003):
	Class of sodium channel antagonist μ-conotoxins, including GIIIA
	Class of calcium channel antagonist ω-conotoxins, including GVIA, GVII, MVIIA, MVIIC, and their analogs or synthetic derivatives
	Class of NMDA-antagonist conantokins, including con-G, con-R, con-T and their analogs or synthetic derivatives
	Putative neurotensin agonist, contulakin-G and its synthetic derivatives
	Junin virus vaccine strain Candid 1 (effective 2-7-2003)
	Yersinia pestis strains which are Pgm- due to a deletion of a 102-kb region of the chromosome termed the pgm locus (i.e., Δpgm). Examples are Y. pestis strain E.V. or various substrains such as EV 76 (effective 3-14-2003)
	Yersinia pestis strains (e.g., Tjiwidej S and CDC A1122) devoid of the 75 kb low-calcium response (Lcr) virulence plasmid (effective 2-27-2003)

	EXCLUDED OVERLAP AGENTS & TOXINS
	Bacillus anthracis strains devoid of both plasmids pX01 and pX02 (effective 2-27-2003)
	Bacillus anthracis strains devoid of the plasmid pX02 (e.g., Bacillus anthracis Sterne, pX01+pX02) (effective 2-27-2003)
	Brucella abortus Strain 19 (effective 6-12-2003)
	Brucella abortus strain RB51 (vaccine strain) (effective 5-7-2003)
	Coxiella burnetii Phase II, Nine Mile Strain, plaque purified clone 4 (effective 10-15-2003)
	Francisella tularensis subspecies novicida (also referred to as Francisella novicida) strain, Utah 112 (ATCC 15482) (effective 2-27-2003)
	Francisella tularensis subspecies holartica LVS (live vaccine strain; includes NDBR 101 lots, TSI-GSD lots, and ATCC 29684) (effective 2-27-2003)
	Francisella tularensis ATCC 6223 (also known as strain B38) (effective 4-14-2003)
	Rift Valley Fever (RVF) virus vaccine strain MP-12 (effective 2-7-2003)
	Venezuelan Equine Encephalitis (VEE) virus vaccine candidate strain V3526 (effective 5-5-2003)
	Venezuelan Equine Encephalitis (VEE) virus vaccine strain TC-83 (effective 2-7-2003)

	EXCLUDED USDA AGENTS & TOXINS
	Highly pathogenic avian influenza (HPAI) virus, recombinant vaccine reference strains of the H5N1 and H5N3 subtypes (effective 5-7-2004)
	Japanese encephalitis virus, SA14-14-2 strain (effective 3-12-2003)

Click Here to visit Select Agent Exclusion website

When complete, click here to return to Main Page

RECOMBINANT DNA (rDNA)

Complete the Gene Source and Vector Desctiption tables below as necessary

Gene Source(s) - ***If more space is needed, attach additional sheets***

Gene Source(s)/Risk Group	Gene Name	Nature of Insert/Protein Expressed	Use of Construct

Vector Description(s) - *If more space is needed, attach additional sheets*			
Vector Type *(plasmid, viral, cosmid, phage)*	**Vector Source** *(Genus, species; if plasmid or viral)*	**Technical Name of Vector**	**Risk Attenuation** *(Replication defective? Helper virus? Disarmed? K-12 derivative?)*

When complete, click here to return to Main Page

ORGAN, TISSUE, or CELL Cultures (OTCC)

Complete the table below as necessary

If more space is needed, attach additional sheets

OTCC *(genus, species, strain)*	**Technical Name** *(e.g. 3T3NIH, Hep2)*	**OTCC Source** *(Select all that apply)*	**Passage** *(Select from list)*	**Comment** *(transforming, oncogenic)*	**Recipient of rDNA Construct?**	**Recipient of Pathogen?**
		Human *Non-Human Primate* *Other*				
		Human *Non-Human Primate* *Other*				
		Human *Non-Human Primate* *Other*				
		Human *Non-Human Primate* *Other*				
		Human *Non-Human Primate* *Other*				
		Human *Non-Human Primate* *Other*				
		Human *Non-Human Primate* *Other*				
		Human *Non-Human Primate* *Other*				
		Human *Non-Human Primate* *Other*				
		Human *Non-Human Primate* *Other*				

When complete, click here to return to Main Page

CHEMICALS ADMINISTERED TO OTCC

Complete the table below as necessary

If more space is needed, attach additional sheets

Nature of Chemical *(carcinogens, mutagens, pesticides, toxins, etc.)*	**Chemical Name**	**Route of Administration (IV, IP, etc.)**	**Highest Concentration Administered**	**Administered to Microbe?**	**Administered to OTCC?**	**Administered to Organism?**

When complete, click here to return to Main Page

BIOSAFETY CABINET (BSC) INFORMATION

Provide number of BSCs in each category and Certification Data as requested

BSC QUANTITIES

CLASS I BSC's	
Enter the total number of Class I BSC's in your facility/facilities:	
Do all Class I BSC's counted above have current certifications?:	

CLASS II TYPE A1 BSC's	
Enter the total number of Class II-A1 BSC's in your facility/facilities:	
Do all Class II-A1 BSC's counted above have current certifications?:	

CLASS II TYPE A2 BSC's	
Enter the total number of Class II-A2 BSC's in your facility/facilities:	
Do all Class II-A2 BSC's counted above have current certifications?:	

CLASS II TYPE B1 BSC's	
Enter the total number of Class II-B1 BSC's in your facility/facilities:	
Do all Class II-B1 BSC's counted above have current certifications?:	

CLASS II TYPE B2 BSC's	
Enter the total number of Class II-B2 BSC's in your facility/facilities:	
Do all Class II-B2 BSC's counted above have current certifications?:	

CLASS III BSC's	
Enter the total number of Class III BSC's in your facility/facilities:	
Do all Class III BSC's counted above have current certifications?:	

BSC CERTIFICATION EXPIRATION DATES

For each Class, list all Certification Expiration Dates (list duplicate dates only once)

NOTE: If more than 14 dates, list earliest (closest) dates

CLASS I	CLASS II-A1	CLASS II-A2

CLASS II-B1	CLASS II-B2	CLASS III

When complete, click here to return to Main Page

ANIMAL RESEARCH and IACUC INFORMATION

Please enter all applicable information in the below table

Use drop-down arrows to enter Animals used, then place an "X" next to all applicable items

ANIMALS	ANIMAL WORK AND TYPES (enter "X" next to all that apply)					
		Arthropod Collection		Inoculation (Oral)		Specific Pathogen Free
		Sample Collection (Lab)		Inoculation (Percutaneous)		Laboratory-Bred
		Sample Collection (Field)		Inoculation (Aerosol)		Wild-Caught
		Surgery		Necropsy		Other Work or Type
		Arthropod Collection		Inoculation (Oral)		Specific Pathogen Free
		Sample Collection (Lab)		Inoculation (Percutaneous)		Laboratory-Bred
		Sample Collection (Field)		Inoculation (Aerosol)		Wild-Caught
		Surgery		Necropsy		Other Work or Type
		Arthropod Collection		Inoculation (Oral)		Specific Pathogen Free
		Sample Collection (Lab)		Inoculation (Percutaneous)		Laboratory-Bred
		Sample Collection (Field)		Inoculation (Aerosol)		Wild-Caught
		Surgery		Necropsy		Other Work or Type
		Arthropod Collection		Inoculation (Oral)		Specific Pathogen Free
		Sample Collection (Lab)		Inoculation (Percutaneous)		Laboratory-Bred
		Sample Collection (Field)		Inoculation (Aerosol)		Wild-Caught
		Surgery		Necropsy		Other Work or Type
		Arthropod Collection		Inoculation (Oral)		Specific Pathogen Free
		Sample Collection (Lab)		Inoculation (Percutaneous)		Laboratory-Bred
		Sample Collection (Field)		Inoculation (Aerosol)		Wild-Caught
		Surgery		Necropsy		Other Work or Type
		Arthropod Collection		Inoculation (Oral)		Specific Pathogen Free
		Sample Collection (Lab)		Inoculation (Percutaneous)		Laboratory-Bred
		Sample Collection (Field)		Inoculation (Aerosol)		Wild-Caught
		Surgery		Necropsy		Other Work or Type

If "Other Work or Type" (in any above item) is selected, enter appropriate information below:

Please enter the appropriate IACUC dates below

IACUC INFORMATION	
Enter the IACUC Approval Date:	
Enter the IACUC Expiration Date:	
Enter the IACUC Exemption Date:	

Please include the IACUC review documentation when submitting this form

When complete, click here to return to Main Page

HUMAN RESEARCH and IRB INFORMATION

Please enter all applicable information in the below form

Use drop-down arrows to place an "X" next to all applicable items

MATERIAL SAMPLE COLLECTION			
	Patients confidentiality is maintained		Samples from healthy patients
	Informed consent obtained from patient		Samples from patients w/ suspected or unknown diagnosis
	Samples collected at hospital/clinic/laboratory		Samples from patients w/ confirmed diagnosis
	Samples collected in the field		Other (explain below)
If "Other" (above) is selected, list/explain below:			

Please enter the appropriate IRB dates below

IRB INFORMATION	
Enter the IRB Approval Date:	
Enter the IRB Expiration Date:	
Enter the IRB Exemption Date:	

Please include the IRB review documentation when submitting this form

When complete, click here to return to Main Page

SELECT AGENTS AND TOXINS LIST (Revised Dec 4, 2012)

Per U.S. Dept of Health and Human Services (HHS) and U.S. Dept of Agriculture (USDA)

HHS SELECT AGENTS & TOXINS
Abrin
Botulinum neurotoxins*
Botulinum neurotoxin producing species of Clostridium*
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)
Cociella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin
South American Haemorrhagic Fever viruses:
Chapare virus
Guanarito Virus
Junin Virus
Machupo Virus
Sabia Virus
Staphylococcal enterotoxins A,B,C,D,E subtypes
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses:
Far Eastern subtype
Siberian subtype
Kyasanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**

OVERLAP SELECT AGENTS & TOXINS
*Bacillus anthracis**
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipa virus
Rift Valley fever virus
Venezuelan Equine Encephalitis virus

USDA SELECT AGENTS & TOXINS
African horse sickness virus
African swine fever virus
Avian influenza virus
Classical swine fever virus
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum
Mycoplasma mycoides
Newcastle disease virus
Peste des petits ruminants virus
Rinderpest virus*
Sheep pox virus
Swine vesicular disease virus

USDA PLANT SELECT AGENTS & TOXINS
Peronosclerospora philippinensis (Peronosclerospora sacchari)
Phoma glycinicola (formerly Pyrenochaeta glycines)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

* Denotes Tier 1 Agent/Toxin

[Click Here to visit Select Agent website]

Click here to return to Main Page

FOR CBEP BIOSAFETY AND BIOSECURITY (BS&S) USE ONLY

SECTION 2A -
NEEDS SECONDARY REVIEW

Biological Materials & Activites	
No	Select Agents & Toxins
No	"Material/Sample" = Isolated Cultures or Toxins
No	"Material Status" = Confirmed Isolates/Toxins
No	"To Be Cultured" = Yes
No	"Infected Host/Model" = Anything other than N/A
No	Production > 10 Liters

Other Materials	
No	rDNA Involvement

OTCC	
No	Source is Human or Non-Human Primate
No	Recipient of rDNA Construct
No	Recipient of Pathogen

SECTION 2D -
NEEDS SECONDARY REVIEW

Biosafety Cabinets	
No	Expired certifications - Class I
No	Expired certifications - Class II-A1
No	Expired certifications - Class II-A2
No	Expired certifications - Class II-B1
No	Expired certifications - Class II-B2
No	Expired certifications - Class III

SECTION 2A -
NEED TO REVIEW SOP's

Biological Materials & Activites	
No	Sample Collection
No	Cryopreservation
No	Injection/Inoculation
No	Culture in Liquid Media
No	Culture on Solid Media

SECTION 2F -
NEED TO REVIEW SOP's

IACUC - Animal Research	
No	Arthropod Collection
No	Sample Collection (Lab)
No	Sample Collection (Field)
No	Surgery
No	Inoculation (Oral)
No	Inoculation (Percutaneous)
No	Inoculation (Aerosol)
No	Necropsy

PASSWORDS	
Unprotect Sheets/Tabs >	BS&S0nly
Unprotect Workbook >	BSandS0nly
Unprotect VB Code >	Gurus0nlyLoL!!

Print all 3 BS&S-Only Tabs

FOR CBEP BIOSAFETY AND BIOSECURITY (BS&S) USE ONLY

CBEP BS&S PROJECT REVIEW ASSESSMENT

Project Number:	***Not Provided***
Project Title:	***Not Provided***

Date Received:		**Review Date:**	

CBEP BS&S Required Level of Review:

BS&S Review Level:	***No Secondary Review Required***
Need to Review SOPs:	***SOP Review is not Required***

Review and Information Summary (by Section):

1 - Info	**1a**	**1b**	**1c**	**1d**	**1e**	**1fr**	**1g**	**1h**		
2 - Info	**2a**	**2b**	**2c**	**2d**	**2e**	**2f**	**2g**	**2h**		
3 - Info	**3a**	**3b**	**3c**							
4 - Info	**4a**	**4b**								
5 - Info	**5a**	**5b**								
6 - Info	**6a**	**6b**	**6c**	**6d**	**6e**	**6f**				

Additional CBEP BS&S Comments:

FOR CBEP BIOSAFETY AND BIOSECURITY (BS&S) USE ONLY

FOR CBEP BIOSAFETY AND BIOSECURITY (BS&S) USE ONLY

CBEP BS&S RECOMMENDATION

Project Number:	***Not Provided***

Project Title:	***Not Provided***

Date Received:		**Review Date:**	

CBEP BS&S Recommendation:

	Approved
	Approved with Modifications (see comments below)
	Not Approved

Assigned/Approved Biosafety Level(s):

	BSL-1
	BSL-2
	BSL-2 + BSL-3 practices
	BSL-3
	BSL-3 Enhanced
	BSL-4

	ABSL-1
	ABSL-2
	ABSL-2 + ABSL-3 practices
	ABSL-3
	ABSL-3 Enhanced
	ABSL-4

Additional CBEP BS&S Comments:

FOR CBEP BIOSAFETY AND BIOSECURITY (BS&S) USE ONLY